

Instructions for use



Sanquin Reagents B.V. Plesmanlaan 125 1066 CX Amsterdam The Netherlands	Phone: +31 20 5123599 Fax: +31 20 5123570 Reagents@sanquin.nl www.sanquin.org/reagents	
Pelikloon anti-Jk^a (IgM) monoclonal	REF K1300	IVD C€ 0344
Pelikloon anti-Jk^b (IgM) monoclonal	REF K1301	IVD C€ 0344
021_v04 07/2019 (en)		<i>For professional use only</i>

Blood grouping reagents for the detection of the Jk^a and Jk^b antigen on human red cells

General information

Pelikloon anti-Jk^a and anti-Jk^b (IgM) monoclonal blood grouping reagents (clone numbers are mentioned on the corresponding certificate of analysis/release document and product label) are prepared from culture supernatants from stable hybridoma cell lines as first described by Köhler and Milstein (Nature 1975). These monoclonal reagents contain human IgM antibodies and have been specially selected and developed to provide a reliable alternative to polyclonal reagents. These reagents meet the requirements of the concerned standards and guidelines. Performance characteristics are mentioned in the release documents, which are supplied with the product upon request. The principle of the test is the agglutination technique, which is based on antigen/antibody reaction. The reagents are optimised for use in the spin tube method. The inclusion of positive and negative controls with each series of blood group determinations is strongly recommended.

Precautions

For in vitro diagnostic use only. Reagents should be stored at 2–8°C. Leaking or damaged vials may not be used. Reagents (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the vial. NaN₃ 0.1% (w/v) is used as preservative. The reagents cannot be assumed to be free from infectious agents. Care must be taken in the use and disposal of each container and its contents. Turbidity may indicate microbial contamination. To recognise reagent deterioration, testing of the reagent as part of the laboratory quality control program using appropriate controls is recommended. Waste-disposal, after completion of the test, should be performed according to your laboratory regulations.

Specimen collection and preparation

Blood samples should be withdrawn aseptically with or without the addition of anticoagulants. If testing of the blood samples is delayed, storage should be at 2–8°C.

Preparation of the specimen is described in the respective test procedures.

Test procedures

Spin tube method

Tube requirements: round bottom glass tubes; size 75 x 10/12 mm.

1. Prepare a 3–5% cell suspension of red cells to be tested in isotonic saline.
2. Add to a test tube:
 - 1 drop of Pelikloon reagent
 - 1 drop of the 3–5% cell suspensionand mix well.
3. Incubate 5 to 15 minutes at roomtemperature (18–25°C).
4. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
5. Resuspend the cells by gentle agitation and read macroscopically for agglutination.

Interpretation

A positive reaction (i.e. agglutination) indicates the presence of the corresponding antigen. A negative reaction (i.e. no visible agglutination) indicates the absence of the corresponding antigen.

Phenotype	Caucasians	Negroids
Jk(a + b +)	50.3%	40.8%
Jk(a + b -)	26.3%	51.1%
Jk(a - b +)	23.4%	8.1%
Jk(a - b -)	rare	rare

Limitations

Unexpected positive results due to: pseudoagglutination, autoagglutination, mixed field reaction, the presence of Whartons jelly together with umbilical cord cells.

Unexpected negative or weak results due to: weak antigens, mixed field reaction, decreased activity of the reagent.

Antigen variant cells may produce unexpected positive or negative reactions with samples previously typed with blood grouping reagents of polyclonal or other cell line-derived monoclonal sources.

False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.

Red cells that have a positive direct antiglobulin test (DAT) may produce false positive test results. Use of Pelikloon control monoclonal (REF K1156) is recommended for Pelikloon anti-Jk^a (IgM) monoclonal and use of Pelikloon enhanced control (REF K1152) is recommended for Pelikloon anti-Jk^b (IgM) monoclonal for detection of such invalid test results.

Pelikloon monoclonal blood grouping reagents have been optimised for use by the technique(s) recommended in this package insert. Unless otherwise stated their suitability for use by other techniques must be determined by the user. Enzyme treated red cells may give a falsely positive reaction with Pelikloon anti-Jk^b reagent.

References

1. Race R.R. and Sanger R.; Blood Groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issit P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Daniels G.; Human Blood Groups. Blackwell Science Ltd. 1995.
4. Reid M.E. and Lomas-Francis C.; The Blood Group Antigen Facts Book. Facts Book Series, 1997.
5. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.

Sanquin products are guaranteed to perform as described in the original manufacturer's instructions for use. Strict adherence to the procedures, test layouts and recommended reagents and equipment is essential. Sanquin declines all responsibility arising from any deviation thereof.